4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0021]

# AbbVie Inc., et al.; Proposal to Withdraw Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen; Opportunity for a Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of March 27, 2014 (79 FR 17156). The document announced an opportunity to request a hearing on the Agency's proposal to withdraw approval of abbreviated new drug applications (ANDAs) from multiple sponsors. The document incorrectly stated that the approval of ANDAs 40825, 40822, and 40824, held by Ranbaxy Laboratories Inc. and Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540, and ANDA 40182, held by Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605, had not been voluntarily withdrawn. FDA confirms that the approval of ANDAs 40825, 40824, 40822, and 40182 has been voluntarily withdrawn.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993-0002, 301-796-5094.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014-06802, appearing on page 17156, in the Federal Register of Thursday, March 27, 2014, the following correction is made:

On page 17157, in table 1, the entries for ANDAs 40825, 40824, 40822, and 40182 are removed. The approval of these applications has been withdrawn under 21 CFR 314.150(d).

Dated: April 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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